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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/506,796	MOR ET AL.
	Examiner	Art Unit
	Bao Qun Li	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9,11-14 and 17-30* is/are pending in the application.

4a) Of the above claim(s) *14 and 17-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-13,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/17/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1, 5-9 and 13 with species of SEQ ID NO: 1 in the reply filed on June 26, 2007 is acknowledged. The traverse is that with amendment of claims 1 and 9, the claims of group II (claims 3, 4, 11 and 12) and group I share a common inventive concept. The compositions and methods of new claims in group I and II are not disclosed in either Barley et al. or Coffier et al. The group I and group II requires a composition comprising one of the recited SEQ ID NOS and an antigen. Therefore, claims 1, 9, 14 and 21 are generic to the elected species. Moreover, Applicant notes that the restriction requirement does not provide sufficient basis to indicate the overly burden for the examiner. Applicants therefore, respectively request reconsideration of group I and group II, claims 1, 3-9, 11-13 and 29-30 to be examined together.

2. Applicant's argument has been fully considered; it has been found persuasive. Claims 1, 3-9, 11-13 and 29-30 are considered.

3. The examiner apologies that claims 22-28 are inadvertently missed in the group II.

4. It is noted: A reasonable interpretation of the road scope of the claimed functional equivalent can be any peptide that is able to induce same immune response against HIV gp41 because all of the peptides sited with defined sequences are derived from HIV gp41.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Durrani et al. (J. Immunol. Methods 1998, Vol. 220, pp. 93-103).

7. Durrani et al. teach a method for inducing immune responses against HIV gp41 and Cholera toxin. The method comprises administering an immunogenic composition comprising HIV gp41 peptide expressed as fusion protein carried by cowpea mosaic virus (CPMV) and cholera toxin that is able to induce an immune response as an antigen as well as adjuvant for the co-administrated antigen gp41 into an animal model (See entire document and pages 97-101). Therefore, claims 1-13 are anticipated by the cited reference.

8. Claims 1, 4, 9, 12, 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Coeffier et al. (Vaccine Vol. 220, pp. 93-103).

9. Coeffier et al. teach a method for inducing immune responses against HIV gp41 and EaIE protein, wherein the antigen of gp41 peptide can be recognized by the antibody 2F5. The method comprises administering an animal model an immunogenic composition comprising fusion protein comprising HIV gp41 peptide fused with EaIE protein. (See entire document and pages 9). Therefore, claims 1, 4, 9, 12, 13 are anticipated by the cited reference.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durrani et al. (J. Immunol. Methods 1998, Vol. 220, pp. 93-103) and Backstrom et al. (a) (Gene 1994, Vol. 149, pp. 211-217) or Backstrom et al. (b) (Gene 1995, Vol. 165, pp. 163-171).

12. The claimed invention is directed to a composition and method for using the composition for inducing an immune response in a subject. The composition comprising HIV gp41 peptide and another peptide antigen of cholera toxin serving as an adjuvant to enhance the mucosal immune response against HIV gp41. Preferably, gp41 peptide, particularly p1 peptide and cholera toxin subunit B (CTB) can be constructed as a fusion protein cited in claims 29-30.

13. Durrani et al. teach a method for inducing immune responses against HIV gp41 and Cholera toxin. The method comprises administering an immunogenic composition comprising HIV gp41 peptide expressed as fusion protein carried by cowpea mosaic virus (CPMV) and cholera toxin that is able to induce an immune response as an antigen as well as adjuvant for the co-administrated antigen gp41 into an animal model (See entire document and pages 97-101). While Durrani et al. teach that cholera toxin is a well known mucosal adjuvant and usually used with other antigen to enhance the other antigen immune response, they do not teach to use cholera toxin with gp41 as a fusion protein, particularly the gp41 peptide is the peptide P1 and cholera toxin is cholera toxin B-unit (CTB).

14. Cholera toxin B is a well known mucosal adjuvant used for produced an enhanced immune response to an antigen that is co-expressed and administered together taught by Backstrom et al. (a) or (b) (See entire documents).

15. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited references and to combine the methods taught by Durrani et al. and Backstrom et al. (a) or (b) to make the gp41 peptide comprising the P1 peptide fused with the cholera toxin B-unit (CTB) and then inject said fusion peptide to a subject for producing an enhanced immune response successfully. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Baoqun Li

Bao Qun Li
12/07/2007

BAOQUN LI, MD
PATENT EXAMINER